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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,544	05/26/2006	Catherine Picart	BJS-3608-8	3195

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1715	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,544	PICART ET AL.	
	Examiner	Art Unit	
	CACHET SELLMAN	1715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-39,42-51,53-65 and 67-76* is/are pending in the application.

4a) Of the above claim(s) *51, 54-65 and 67-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39, 42-50,53, and 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 47, 75 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47, 75 and 76 have an improper Markush group. “When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if “wherein R is a material selected from the group consisting of A, B, C and D” is a proper limitation, then “wherein R is A, B, C or D” shall also be considered proper. See MPEP 2173.05(h)

3. Claim 47 should read “…wherein the polyelectrolyte multilayers comprise materials selected from synthetic polyions, biopolymers, proteins, enzymes, cells, viruses, dendrimers, colliods, inorganic partices, organic particles, dyes, vesicles, nanocapsules, microcapsules, nanoparticles, microparticles, polyelectrolytes complexes, free drugs, complexed drugs, cyclodextrins, **or** mixtures thereof."

4. Claim 75 should read “…wherein the biopolymers are selected from DNA, RNA, collagen **or** peptides

5. Claim 76 should read “…wherein the peptides are selected from a RGD sequence, Melanoma stimulating Hormone **or** buforin.”

Response to Amendment

6. The declaration under 37 CFR 1.132 filed 4/15/2011 is insufficient to overcome the rejection of claims 37, 38, 39, and 42-50 based upon Qiu et al. applied under 35 U.S.C. 102 (a) as set forth in the last Office action because the declaration states the process was followed as described by Qui et al. and a "spectra was obtained before and **after cross-linking** of the (PAH/PAA) film," the inclusion of a spectra performed after cross-linking is evident there was cross-linking of the films. The spectra provided shows one line for the reaction of PAH/PAA after exposure to the coupling agent of NHS but does not show the initial spectra before exposure to the NHS, in order to for a comparison to be made between the two spectras to validate the claim there is no crosslinking in the process described by Qiu et al.

Response to Arguments

7. Applicant's arguments filed 4/5/2011 have been fully considered but they are not persuasive. Applicants argue the process of Qiu et al. does not result in crosslinking of the layers. However, this contradicts that which is stated in the specification of the current application, specifically page 4, lines 6-20 which states the addition of the NHS agent aids in the crosslinking of the carboxylic acid and amino groups in the two polyelectrolyte materials. Furthermore, in the arguments it states the process was followed as described by Qui et al. and a "specrta was obtained before and **after cross-linking** of the (PAH/PAA) film," which shows there is some crosslinking of the film. The spectra provided shows one line for the reaction of PAH/PAA after exposure to the coupling agent but does not show the initial spectra before exposure to the NHS, in

order to compare the two lines showing a different between the two and support the claim there is no crosslinking in the process described by Qiu et al.

8. Applicants further argue there is only one layer of electrolyte being formed in the process of Qiu et al. However, the Examiner disagrees, Qiu et al. clearly teaches multiple layers can be formed by using multiple dips in order to achieve a desired thickness (see of Qiu et al. 0198).

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 37-39, 42-50 and 73-75 are rejected under 35 U.S.C. 102(a) as being anticipated by Qiu et al. (US 2003/01433335) and (Admitted Prior Art for support, found in specification page 4, lines 6-20).

As to claim 37, Qiu et al. discloses a process of coating contact lenses with a multilayer of polyelectrolytes of polyacrylic acid (supplies carboxylic groups) and poly(allyl amine hydrochloride) (supplied amino groups, see paragraph 0014) by dipping the contact into a solution of each polyelectrolyte, the contact lens is then activated by soaking the coated lenses into a solution of 1-(3-dimethylaminopropyl)-3-ethylcarbodiimide hydrochloride) (EDC, coupling agent) and sulfo-N-hydroxysuccinimide (NHS) (see Example K paragraph 0400). As to the limitation of crosslinking, as stated in the admitted prior art, the use of the NHS in the reaction between the carboxylic group and the amino groups results in the crosslinking between the layers (see page 4, lines

6-20 of the specification).Qiu et al. teaches 5 pairs of the electrolytes can be applied by successive dips into each solution in order to achieve the desired thickness (see 0198).

As to claim 38, the multilayers are assembled via electrostatic attraction (see 0012-0013).

As to claim 39, the layers are biocompatible (i.e. they are used on contact lenses).

As to claim 42, the amino groups and carboxylic groups are attached by covalent bonds (see paragraph 0205).

As to claims 43-45, the cationic polyelectrolyte (PAH) supplies the amino groups and the anionic polyelectrolyte (PAA) supplies the carboxylic groups.

As to claim 46, the multilayers can further comprise polymers with different functional groups (see paragraph 0107).

As to claim 47, the multilayers can comprise a variety of materials such as dyes, bioactive agents (see 016-168).

As to claim 48-50, the coupling agent is EDC.

As to claim 73, the multilayers are assembled using electrostsatic attraction and hydrogen bonding (see 0012).

As to claim 74, the anionic polyelectrolyte can be hyaluronic acid or heparin (see 0108).

As to claim 75, the biopolymer can be peptides or collagen (see 0167 and 168).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qiu et al. as applied to claim 37 above in view of Lennon et al. (US 5721361).

The teachings of Qiu et al. as applied to claim 37 are as stated above.

Qiu et al. fail to teach the use of N-hydroxysulfosuccinimide para-nitrophenol with the coupling agent as required by claim 37.

Qui et al. does teach the use of N-hydroxysulfosuccinimide with the coupling agent.

However, Lennon et al. discloses coupling agents which are capable of coupling a carboxylic acid group with a terminal amine group to form an amide bond between the two materials. Lennon et al. discloses various types of coupling agents such as NHS which can be used in conjunction with a coupling agent from another group such as EDC and p-nitrophenol (see col. 16, line 65 - col. 17, line 51).

It would have been obvious to one having ordinary skill in the art to use the NHS-para nitrophenol with the coupling agent of Qiu et al. through routine experimentation especially since Lennon et al. teaches such agents are capable of forming an amide bond between carboxylic and amine groups which is desired in Qiu et al. also, especially since simple substitution of one known element for another would have predictable results.

13. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qiu et al. as applied to claim 47 above in view of Rubner et al. (US 2003/0157260).

The teachings of Qiu et al. as applied to claim 47 are as stated above. Qiu et al. teaches the use of peptides in the multilayers (see 167-168) but fails to teach the specific peptides of claim 76.

However, it was well known in the art to providing polyelectrolyte multilayers where a variety of cell adhesive biomolecules to the multilayers such as RGD by chemically modifying materials such as PAA, PMA or PAH (see 0043 of Rubner et al.).

It would have been obvious to one having ordinary skill in the art to modify the process of Qiu et al. to include the peptides of Rubner et al. in order to provide cell adhesive biomolecules to the multilayered structure aiding in cell adhesion depending upon the type of medical device being coated especially since both disclose the use of the same polyelectrolytes and Rubner et al. further teaches operable peptides that can be used.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 8:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman

Examiner
Art Unit 1715

/C. S./
Examiner, Art Unit 1715

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1715